

SUPPORT FOR THE AMENDMENTS

Claims 8-15 have been canceled.

Claims 25, 26, and 31-33 have been amended.

Claims 34-36 have been added.

Claims 25 and 26 are amended to add a period to the end of these claims. The amendment of Claims 31-33, as well as new Claims 34-36, is supported by the originally presented claims and the specification as filed and the Examples.

No new matter has been added by the present amendment.

REMARKS

Claims 1-7 and 16-36 are pending in the present application.

The rejection of Claims 31-33 under 35 U.S.C. §112, second paragraph, is obviated by amendment.

Claims 31-33 have been amended to remove the objected to “the reagent”. Accordingly, this ground of rejection is believed to be moot.

Withdrawal of this ground of rejection is requested.

The rejection of Claims 8-10 under 35 U.S.C. §102(a) over Yabuki et al is obviated by cancellation of these claims. Applicants make no statement with respect to the propriety of this ground of rejection and in no way acquiesce to the same. Indeed, for the reasons given below for the rejection over the combined disclosures of Rosenberg et al, Labows et al, and Yabuki et al, Yabuki et al is Applicants own work and, thus, is not available as “prior art” under 35 U.S.C. §102(a). Nonetheless, to expedite examination of Claims 31-36, Applicants have canceled Claims 8-10. Therefore, this ground of rejection is now moot.

Withdrawal of this ground of rejection is requested.

The rejection of Claims 8-10 and 31-33 under 35 U.S.C. §103(a) over Rosenberg et al in view of Labows et al and Yabuki et al is obviated by the correction of inventorship herewith.

Rosenberg et al and Labows et al are discussed below. However, this ground of rejection is not tenable. Specifically, Yabuki et al is Applicants own work and is not available as “prior art”. As such, this ground of rejection cannot be maintained.

To this end, the Examiner is reminded that the present application was filed on December 16, 2005, as a National Stage (371) of PCT/JP03/12793, filed October 6, 2003.

Yabuki et al published on October 8, 2002, which is less than one year prior to the effective filing date of the present application (i.e., the filing date of the International Application - October 6, 2003). Accordingly, Yabuki et al can only be available as “prior art” under 35 U.S.C. §102(a).

35 U.S.C. §102(a) states:

A person shall be entitled to a patent unless ...

- (a) the invention was known or used *by others* in this country, or patented or described in a printed publication in this or a foreign country, *before the invention thereof by the applicant* for patent, or

Accordingly, only work that is by “another” may qualify as art under 35 U.S.C.

§102(a).

The authors of Yabuki et al are listed as Masayuki Yabuki, Yoshihiro Hasegawa, and Masamoto Matsukane. In view of the correction in the inventorship of this application set forth in the Petition under 37 C.F.R. §1.48(a) submitted herewith, the inventors of the present application are Masayuki Yabuki, Yoshihiro Hasegawa, and Masamoto Matsukane. Thus, the disclosure by Yabuki et al is Applicants own work. Therefore, this ground of rejection is not tenable.

Withdrawal of this ground of rejection is requested.

The rejection of Claims 8-10 and 31-33 under 35 U.S.C. §103(a) over Rosenberg et al in view of Labows et al and Natsch et al is respectfully traversed.

Applicants make no statement with respect to the propriety of this ground of rejection as applied to Claims 8-10 and in no way acquiesce to the same. Solely to expedite examination of Claims 31-36, Applicants have canceled Claims 8-10.

The invention of Claims 31-36 is drawn to a methods of assessing body odor of a human comprising steps of:

- a first step of extracting a mixture of  $\beta$ -hydroxycarboxylic acid and fatty acid having 12 or less carbons other than said  $\beta$ -hydroxycarboxylic acid from perspiration of a human;

- a second step of adding a coloration reagent which reacts with the  $\beta$ -hydroxycarboxylic acid and/or the fatty acid having 12 or less carbon atoms other than said  $\beta$ -hydroxycarboxylic acid to the mixture to exhibit color; and

- a third step of assessing the kind and/or strength of body odor from the color exhibited in the second step. (see Claim 31)

\* \* \*

- a first step of extracting a mixture of  $\beta$ -hydroxycarboxylic acid and fatty acid having 12 or less carbons other than said  $\beta$ -hydroxycarboxylic acid from perspiration of a human;

- a second step of separating  $\beta$ -hydroxycarboxylic acid from the mixture;

- a third step of reacting said  $\beta$ -hydroxycarboxylic acid separated in the second step with a coloration reagent which reacts with the  $\beta$ -hydroxycarboxylic acid and/or the fatty acid having 12 or less carbon atoms other than said  $\beta$ -hydroxycarboxylic acid to exhibit color; and

- a fourth step of assessing the kind and/or strength of body odor from the color exhibited in the third step. (see Claim 32)

\* \* \*

- a first step of extracting a mixture of  $\beta$ -hydroxycarboxylic acid and fatty acid having 12 or less carbons other than said  $\beta$ -hydroxycarboxylic acid from perspiration of a human;

- a second step of separating the mixture into  $\beta$ -hydroxycarboxylic acid and fatty acid having 12 or less carbons other than said  $\beta$ -hydroxycarboxylic acid respectively;

a third step of reacting said  $\beta$ -hydroxycarboxylic acid separated in the second step with a coloration reagent which reacts with the  $\beta$ -hydroxycarboxylic acid to exhibit color;

a fourth step of reacting said fatty acid having 12 or less carbons other than said  $\beta$ -hydroxycarboxylic acid separated in the second step with a coloration reagent which reacts with the fatty acid having 12 or less carbon atoms other than said  $\beta$ -hydroxycarboxylic acid to exhibit color; and

a fifth step of assessing the kind and/or strength of body odor from each of the colors exhibited in the third and fourth steps. (see Claim 33)

The substances used as indexes in this method are quite similar to apocrine odor of axillary regions and are specifically present in a person who has apocrine odor. 3-hydroxy-3-methylhexanoic acid is specifically present in axillary regions of a person who has apocrine odor. The apocrine odor is stronger in a person who has more 3-hydroxy-3-methylhexanoic acid contained in the perspiration of the axillary regions. The present inventors have found that 3-hydroxy-3-methylhexanoic acid contributes to a spicy cumin-like odor, which is a particularly important component of odor among major bad odors constituting the apocrine odor.

Also, the inventors have found that, among odor components of several kinds of body odors, the presence amount of  $\beta$ -hydroxycarboxylic acid having a cumin-like odor is strongly related to and the level of body odor, and considered that  $\beta$ -hydroxycarboxylic acid can be used as an indicator material. The  $\beta$ -hydroxycarboxylic acid compound represented by Formula (1), which is a group of compounds having a chemical structure quite similar to 3-hydroxy-3-methylhexanoic acid, is similar in characteristics such as chemical characteristics and organoleptic characteristics (particularly, odor) to 3-hydroxy-3-methylhexanoic acid, thus, the  $\beta$ -hydroxycarboxylic acid compound can be used as an objective index for assessing apocrine odor similarly to 3-hydroxy-3-methylhexanoic acid. The  $\beta$ -hydroxycarboxylic acid compound including 3-hydroxy-3-methylhexanoic acid can be separated from other

substances which are low in contribution to the apocrine odor utilizing differences in polarity, solubility or the like.

The inventors of the present invention have discovered that 3-mercapto-3-methylhexanol and a 3-mercapto alcohol compound, which is a group of compounds having a chemical structure quite similar thereto, are specifically present in the person who has the apocrine odor and the apocrine odor is stronger in a person who has more 3-mercapto-3-methylhexanol and 3-mercapto alcohol compound contained in the perspiration of the axillary regions. 3-mercapto-3-methylhexanol and 3-mercapto alcohol compound contribute to a fishy sulfur-like odor of the apocrine odor. As the 3-mercapto alcohol compound has not only a hydroxyl group but also a mercapto group at the 3-position, the derivative which is chemically modified can also be used as an index for assessing apocrine odor.

With respect to the method of assessing body odor according to Claims 31-36, these claims relate to a method where the level of apocrine odor itself or a total body odor with focus on apocrine odor can be surely and easily assessed from the color exhibited by reacting  $\beta$ -hydroxycarboxylic acid and fatty acid having 12 or less carbons other than the  $\beta$ -hydroxycarboxylic acid, which are separated from perspiration of human, with a coloration reagent respectively. According to the assessment methods of Claims 31-36, not only strength of odor but also a kind of odor can be assessed by the exhibited colors.

Specifically, not only a level of the apocrine odor but also a level of total odor of the apocrine odor with acid odor can be quickly and easily assessed. For example, the assessment of the total odor originated from both  $\beta$ -hydroxycarboxylic acid (primarily causes the apocrine odor) and fatty acid having 12 or less carbons other than said  $\beta$ -hydroxycarboxylic acid (primarily causes acid odor), and also the assessment of the apocrine odor originated from  $\beta$ -hydroxycarboxylic acid can be performed together by adding a

coloration reagent respectively to acid material extracted from perspiration, and  $\beta$ -hydroxycarboxylic acid separated from the acid material, and observing the exhibited colors. Specifically, these method permit a level of contribution of apocrine odor and acid odor in axillary odors to be quickly and easily assessed by the assessment of total odor thereof and the apocrine odor.

Alternatively, a level of contribution of apocrine odor and acid odor in axillary odor can be assessed by separating an acid material extracted from perspiration of a human into  $\beta$ -hydroxycarboxylic acid, which causes apocrine odor, and fatty acid having 12 or less carbons other than said  $\beta$ -hydroxycarboxylic acid, which causes acid odor, and adding a coloration reagent thereto respectively to observe the exhibited colors.

The results demonstrated in Examples C to E illustrate that, in accordance with the present invention, the presence or contribution of the apocrine odor together with acid odor can be assessed.

Particularly, in the case of using a compound having a hydrazino group such as 2-nitrophenylhydrazine as a coloration reagent, sensitivity in detecting  $\beta$ -hydroxycarboxylic acid originated from the perspiration of a human is increased and the colorimetry test with the naked eye can be easily performed. Also, in the case of using a compound having a diazomethyl group such as 9-anthryldiazomethane as a coloration reagent, sensitivity in detecting  $\beta$ -hydroxycarboxylic acid is increased and the reaction proceeds under a mild condition without catalyst and heating, therefore, the assessment is easily performed.

With the foregoing in mind, Applicants provide the following discussion with respect to the cited art. Natsch et al disclose an invention whose object is to prevent or suppress human malodor, in particular human axillary malodor. More specifically, Natsch et al discloses that essentially odorless precursor compounds (substrates of enzyme) in sweat are

cleaved by an enzyme to release malodorous compounds such as 3-hydroxy-3-methyl-hexanoic acid having a pungent odor. Also, Natsch et al disclose that 3-hydroxy-3-methyl-hexanoic acid dehydrates to give 3-methyl-3-hexenoic acid which is another key component of human axillary malodor.

Rosenberg et al disclose a method for gauging the presence and level of oral malodor based on the estimation of the activity of  $\beta$ -galactosidase, which is an enzyme producing an odor substance contributing to oral malodor. As a specific example of the method for the assessment of the enzyme activity, a color reaction is used. Also, in Rosenberg et al, the assessment substance is an enzyme which produces an odor substance, and not the odor substance itself. It means that human malodor (oral malodor) is indirectly gauged.

Labows et al disclose low reliability of organoleptic tests of body odor, and plural components including short-chain fatty acids such as 3-methylhexenoic acid as the causative agents of axillary odor.

However, it is not disclosed nor implied in any of the above cited documents that 3-mercapto alcohol compound represented by Formula (3) and the derivative of 3-mercapto alcohol compound represented by Formula (4) in the specification of the present application contribute to apocrine odor, particularly, sulfur-like odor. Hence, it is not disclosed nor implied that a mixture containing 3-hydroxy-3-methyl-hexanoic acid and 3-mercapto alcohol compound and/or a derivative thereof has an odor similar to apocrine odor.

In addition, there is no disclosure or suggestion in any of the above cited documents about the importance of 3-hydroxy-3-methyl-hexanoic acid as a causative agent of axillary odor and the quality of its odor. Natsch et al disclose 3-hydroxy-3-methyl-hexanoic acid and 3-methyl-3-hexenoic acid as causative agents of axillary odor, but does not disclose at all about the difference of these odors in types and level of contribution to axillary odor. Hence,



there is no motivation, in any of the above cited documents, to select 3-hydroxy-3-methyl-hexanoic acid as an indicator of body odor of a human among plural causative agents of axillary odor disclosed in the above cited documents.

Specifically, the above cited documents do not disclose nor imply a method for assessing body odor of a human using  $\beta$ -hydroxycarboxylic acid represented by 3-hydroxy-3-methyl-hexanoic acid together with a 3-mercapto alcohol compound represented by 3-mercapto-3-methylhexanol and/or a derivative thereof as indicators, and that assessing axillary odor excellent in reproducibility of actual apocrine odor is capable by the method.

Therefore, Applicants submit that the skilled artisan would not conceive of the assessment method of amended Claim 8 of the present application and the claims dependent therefrom even when considering the combined disclosures of Rosenberg et al, Labows et al, and Natsch et al.

Also, Natsch et al, as aforementioned, disclose that 3-hydroxy-3-methyl-hexanoic acid has a pungent odour of axillar, however, there is no mention about difference in types of odor between 3-hydroxy-3-methyl-hexanoic acid and fatty acids having 12 or less carbon atoms other than  $\beta$ -hydroxycarboxylic acid such as 3-methyl-3-hexenoic acid.

Specifically, Natsch et al do not disclose nor imply that  $\beta$ -hydroxycarboxylic acid and fatty acid having 12 or less carbon atoms other than  $\beta$ -hydroxycarboxylic acid contribute to different types (quality) of body odor of a human such that  $\beta$ -hydroxycarboxylic acid represented by 3-hydroxy-3-methyl-hexanoic acid contributes to cuminal-like apocrine odor while fatty acid having 12 or less carbon atoms other than  $\beta$ -hydroxycarboxylic acid contributes to acid odor. In addition, Natsch et al do not disclose nor imply that the comprehensive strength and quality of body odor of a human, particularly, axillary odor, and the level of contribution to the body odor by each odor substance are assessed by separating

$\beta$ -hydroxycarboxylic acid represented by 3-hydroxy-3-methyl-hexanoic acid and fatty acid having 12 or less carbon atoms other than  $\beta$ -hydroxycarboxylic acid from sweat collected from an axillary region, and analyzing each substance at the same time.

Also, Rosenberg et al do not disclose nor imply that the comprehensive strength and quality of body odor of a human, particularly, axillary odor, and the level of contribution to the body odor by each odor substance are assessed by analyzing each of plural odor substances different in odor types at the same time.

In Labows et al, as aforementioned, plural components including short-chain fatty acids such as 3-methylhexenoic acid are mentioned as the causative agents of axillary odor, however, there is no mention about difference in odor types between these fatty acids and  $\beta$ -hydroxycarboxylic acid such as 3-hydroxy-3-methyl-hexanoic acid.

That is, Labows et al do not disclose nor imply that  $\beta$ -hydroxycarboxylic acid and fatty acid having 12 or less carbon atoms other than  $\beta$ -hydroxycarboxylic acid contribute to different types (quality) of body odor of a human such that  $\beta$ -hydroxycarboxylic acid represented by 3-hydroxy-3-methyl-hexanoic acid contributes to cumin-like apocrine odor while fatty acid having 12 or less carbon atoms other than  $\beta$ -hydroxycarboxylic acid contributes to acid odor. In addition, Labows et al. does not disclose nor imply that the comprehensive strength and quality of body odor of a human, particularly, axillary odor, and the level of contribution to the body odor by each odor substance are assessed by separating  $\beta$ -hydroxycarboxylic acid represented by 3-hydroxy-3-methyl-hexanoic acid and fatty acid having 12 or less carbon atoms other than  $\beta$ -hydroxycarboxylic acid from sweat collected from an axillary region, and analyzing each substance at the same time.

Therefore, Applicants submit that the skilled artisan would not conceive of the assessment method of amended Claims 31-36 of the present invention and the claims

dependent therefrom even when considering the combined disclosures of Rosenberg et al, Labows et al, and Natsch et al.

Withdrawal of this ground of rejection is requested.

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

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